

LABORATORY CERTIFICATION STANDARDS REVIEW COUNCIL
MEETING MINUTES FROM 11/13/97

Attendance

Staff: Jack Sullivan, Mike Kvitrud, Alfredo Sotomayor and Jeff Ripp

Council Members: Gilbert Williams (Vice-chair), David Kollakowsky, Ruth Klee Marx, Bill Sonzogni, Debbie Cawley, Barb Hill, Bill Bruins and Russ Janeshek. The absence of Mary Christie (Chair) was previously excused thus all Council members were accounted for.

Guests: Barb Burmeister (SLH), Laura Forst (DATCP), Paul Harris (Davy Labs), Paul Junio (NET, Inc.), Ron Krueger (Northern Lake Services), Art Lautenback (Robert E. Lee)

Action Item Summary

- The previous meeting's minutes were accepted.
- The Council accepted the draft technical advisory committee proposal for NELAP adoption.
- The Council requested to be kept informed of the technical advisory committee's progress.
- The Council members will gather comments and make recommendations for the NR 149 rule change.

Agenda Items

- I. Approval of August 14, 1997 Meeting Minutes
 - A. It was mentioned that ATCP 77, Wis. Adm. Code would also need to be changed if the microbiological certification program was to become NELAP accredited.
 - B. **A motion was made by Mr. Janeshek to accept the August 14, 1997 meeting minutes, it was seconded by Mr. Kollakowsky and the minutes were unanimously approved with the addition of ATCP 77 to section VI. B. 1. of the draft minutes.**
- II. Laboratory Certification Program Updates
 - A. Program Status
 1. With the coming of NELAP, the program will begin focusing on in-state labs to the extent possible.
 2. The program is down to 10 labs that have never been seen.
 3. The new auditors have completed their training and are now conducting observed audits.* They will soon be doing the majority of the audit workload.
 4. The Western Central Region LTE position was converted to a half-time FTE position and filled. The plan is to, overtime, convert at least one additional regional LTE position to half-time FTE.
 - B. Budget Report
 1. A fiscal year (FY) 1998 proposed budget was distributed and explained.
 2. The spending authority for the program was lowered by ~\$7K from the time the program budgeted (~468K) to the time it was approved in the Governor's budget (~\$461K). It is not known at this time why this happened, but the program is trying to raise it to what it was previously.
 3. The spending authority regulates how much the program can spend in one year. It also is the cap on the amount of money the program can collect in fees using the fee formula.
 4. The state budget provided for a 3% raise to state employees (including program staff), however, resources were not allocated for this expense. Many state agencies may pay for these raises by not filling vacancies; however, the Lab Certification program does not have

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this as a viable option and will likely cut back on its contract auditor's hours to meet this revenue need.

5. The beginning of the year balance is almost to where it is supposed to be, the program should have a full year's operating expenses to start each FY year.
6. The program projects its FY 1998 expenses to exceed the program's spending authority. This is prohibited by statute; therefore, the program also intends to initiate a one-time increase in its spending authority to accommodate for the unbudgeted expense of the Oracle conversion.
7. **The Council asked what these increases in spending authority would mean for the labs' fees.** The program made a rough projection of a 15% increase in fees next year if the increases in spending authority were approved. The Council Vice-chair asked the commercial laboratory guests if they were comfortable with the fee increase. The guests said they were not opposed to a fee increase. Both Council members and guests said the cost of Wisconsin certification is on the lower range of other state's certifications and was a "deal".
8. There was a discussion of the lab tracking system Oracle conversion.
 - a. Any software has the same upgrade situation and by continuing to use Oracle, the program may tie its lab information into the Department's other databases.
 - b. **Mr. Williams asked how long the new system would last before another conversion would be necessary.** No one really knows, but the program assumes it will not need another major conversion for many years. The lab tracking system will need some minor changes if NELAP is implemented in Wisconsin.*

III. NELAP

A. The Department's Role in NELAP Process

1. The Department has been active in the creation of the national standards. Now the Department wishes to step back and get a recommendation from the public. It will form a technical advisory committee (TAC) which will make the recommendations on whether to adopt NELAP in Wisconsin and if so, how to implement the adoption.
2. A working draft proposal of the TAC was distributed and explained.
 - a. The TAC will need to consist of a diverse group of affected parties, but must remain small enough as to not impede the process.
 - b. Two sub-committees may be arranged; one to compare the standards and one to look at implementation of NELAP.
3. The Department will form the TAC and set-up a timeline upon approval of the Council.
4. Mr. Sullivan will consult with the Department's legal services to determine whether any statutory changes will be necessary to adopt the NELAP standards.

B. The Council's Role in NELAP Process

1. The Council was encouraged to have at least one member active in the TAC and to make recommendations on its composition.
2. **The Council and guests mentioned several suggestions for the TAC composition.**
 - a. It should mainly consist of people (labs) who would be directly regulated by NELAP.
 - b. Microbiological labs may not be represented in the current draft proposal.
 - c. The Wastewater Operator's Association (WWOA) should be included in draft proposal.
3. **A motion was made by Ms. Hill, seconded by Mr. Kollakowsky and unanimously carried to approve the working draft TAC proposal with the above mentioned additions.**
4. **The Council requested to be kept informed of the TAC's progress.**

C. A Discussion of NELAP took place

1. **Several guests wanted the adoption of NELAP to happen quickly in Wisconsin. They**

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liked the idea of the TAC, but wanted it on a fast track.

2. **Several guests and Council members stated that the data quality standards should not be different for certified and registered labs.** The main conflict of adoption will be the cost of certification vs. registration. Ms. Hill suggested that separate fees are advantageous to both types of labs. It keeps the cost of operating a registered lab lower, but at the same time discourages those labs from becoming certified and analyzing other's samples.
3. Ms. Hill mentioned that more reciprocity labs would allow the program to collect fees without the associated audit workload.
4. Several guests and Council members stated they wished to be audited on NELAP's 2 year cycle and liked the idea of in-state labs receiving more visits than the current system allows.
5. **Several guests mentioned that Wisconsin's program was superior to others and they did not want it to digress when NELAP is implemented.** Specifically, they did not like solely "checklist audits" and wanted Wisconsin's thorough audit process to continue.
6. **The Council and guests were concerned about different states' ability to enforce the standards consistently.**

IV. Results of the Council's Survey on Rating Deficiencies

- A. The point was made that the context of a deficiency was needed to determine its importance. Since reports only contain deficiencies, people may have differing views on their importance because of the lack of context surrounding them.
- B. General items such as lack of quality control (QC) were easily and consistently rated, while specific examples of those deficiencies varied in how they were rated.
- C. The Council's results were different from those of the program's staff. The program's staff results were also different depending on what function they performed. This showed the importance of a deficiency also changes depending on the position (job) of the rater.
- D. **Several people suggested that laboratories should also take the survey.** This would require a significant portion of program staff time to analyze more results.
- E. The program plans to use the results of the survey to begin an importance ranking system for deficiencies. This system would need to be flexible enough to accommodate the context of the deficiency as well as the deficiency itself.

IV. Enforcement Discussion

- A. The goal of enforcement is to gain compliance.
- B. There are 3 steps to the enforcement process.
 1. The notice of non-compliance (NON) is a "friendly" enforcement phase. It is the first step which recognizes alleged non-compliance and can be issued by the program without legal or enforcement consultation.
 2. The notice of violation (NOV) is more severe than the NON. It is in this step that the Department's legal and enforcement services are notified of the violations and consulted.
 3. The order is a final action issued by the Department. This step can be appealed by the party receiving the order. It is usually in the form of an order of revocation for the areas in which compliance is not being met. A consent order may also be used as a contract or agreement between the Department and a laboratory to establish a timeline for compliance.
- C. Ms. Hill described New Jersey's automated enforcement system in which their computer issues unnecessary enforcement because it's lack of information and discretion. Their staff then need to repeal those enforcement actions.
- D. **Mr. Bruins inquired what the timeline of the enforcement process was.**
 1. Currently, there is no set time to comply before the enforcement is either issued or escalated to the next step.
 - a. This is dependent on the willingness and ability of both the lab and the auditor to

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- resolve the compliance issue.
- b. The program may specify a timeline to comply in either the audit report or in the enforcement notice.
- c. A Council member stated that other states do have set timelines for compliance.
- 2. The time to appeal an order is set at 30 days from the date the order is issued.
- E. The process of determining enforcement was explained.
 - 1. There are three types of violations.
 - a. Direct violation - violations of actual NR 149, Wis. Adm. Code citations (e.g. process a blank on each analysis day)
 - b. Once removed violation - violations of general NR 149, Wis. Adm. Code citations (e.g. maintain proper calibration as specified by the method)
 - c. Twice removed violation - violations of a method cited in another Wis. Adm. Code.
 - d. These are increasingly harder to enforce as they become farther from direct NR 149 citations.
 - 2. The severity of a deficiency is moderated by its context.
 - a. The length of time the deficiency has occurred.
 - b. The amount of data the deficiency influenced.
 - c. Whether the deficiency affected more than one testing area.
 - d. Whether the deficiency has been cited before.
 - e. Whether the deficiency was an oversight or intended (mistake vs. falsification).
 - f. A Council member also mentioned the impact to the environment (a potential for false positives is more protective than a potential for false negatives).
 - 3. The auditors must think about all of these when considering enforcement.
 - 4. If compliance can be gained quickly, enforcement may not be needed.
- F. Issuing enforcement interrupts a laboratory's ability to apply or become certified or registered in other areas until compliance is met in the deficient area.
- G. **Ms. Hill would like to see area-specific enforcement because one area of a laboratory may be in compliance while another area may be out of compliance.**
- H. The NELAP standards do not specify enforcement procedures. This will be left to the states' laws and regulations.
- I. **The Council and guests were concerned that states' may not use enforcement consistently.** NELAP will have a committee to investigate complaints of uneven application of standards and enforcement between states.

VI NR 149 Rule Change

- A. The changes were summarized and explained.
- B. **The Council wanted to discuss authoritative sources.**
 - 1. The authoritative sources in NR 149, Wis. Adm. Code are simply a list of methods or method manuals which are recognized by the Department. By placing new or updated methods in the authoritative sources, the program is giving the option for both laboratories and other DNR programs to choose new and updated methods of analysis.
 - 2. The Department's programs prescribe which methods are acceptable in their individual codes (NR 507, 809, 219, 700, etc...). If the codes do not specify a method, then an appropriate method from the authoritative sources may be chosen.
- C. **The Council wanted to discuss the proposed category 21, "Immunoassay".**
 - 1. By creating the category for immunoassay, the LabCert program is getting ready for its use and regulation but not immediately implementing it. The individual programs (wastewater, drinking water, & remediation) will be the ones who eventually decide on whether or not to accept and use the new methods.
 - 2. When it is used for making Department decisions or choosing which samples will be sent for

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additional analysis, immunoassay standards will have to be set and the Department would need to review the procedures.

3. **The Council was concerned that the program would then need to certify another entirely different group of people (mobile labs and consultants).** The program has already offered certification to mobile laboratories, but none have been able to meet Wisconsin's certification requirements. Certification would not be necessary for everyone who performs immunoassay, just as it is not necessary for all laboratories to be certified or registered.
 4. Not all assays would be acceptable, the program would only offer certification for specific methods or kits.
- D. **The Council members will gather comments from the parties they represent and make with recommendations for the NR 149 rule change by the end of the public comment period (December 20, 1997).**

VII. Amended Agenda Items

- A. SW-846 Update III Incorporation into NR 149
 1. **Several Council members and guests were concerned that Update III of SW-846 contained a volatile method (5035) with preservation requirements which conflicted with NR 700.13, Wis. Adm. Code.**
 2. The authoritative sources in NR 149 are an option only if the method isn't specified in another program's code. Since NR 700.13 requires specific methanol preservation techniques, SW-846 5035 will not be usable to comply with the NR 700 series (Spills).
- B. Drinking water (SDWA) reference samples
 1. **Ms. Marx wanted to know when the last EPA Water Supply (WS) study was and what the Department planned to do after then.**
 2. The last EPA WS study is #41 in June of 1998.
 3. The Department will continue to require that SDWA certified labs analyze the EPA's WS samples until they are no longer available.
 4. To prepare for the future, language was added to the proposed NR 149 code change to allow the use of other provider's samples as long as they met the levels and grading criteria prescribed by the EPA for drinking water samples. Currently APG and ERA have WS studies which meet these requirements and the State Lab of Hygiene is also looking into this.

VIII. Future Meeting Date

- A. The next LabCert Standards Review Council meeting was tentatively set for Thursday, February 12, 1998.
- B. The program will work with the Chair to set up the next meeting.
- C. The Council members should contact the Chair or Vice-chair to get items on the next meeting's agenda.

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